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Serial Number: 10/788,906 Filing Date: February 27, 2004

Title: METHOD AND APPARATUS FOR DEVICE CONTROLLED GENE EXPRESSION

### **REMARKS**

This responds to the Office Action dated on December 4, 2007.

Claims 1-3, 32-34 and 57-58 are amended. Claims 1-7, 10-38, 41-148, and 150-151 are now pending in this application.

# Claim Objections

Claim 63 was objected to for informalities. The status identifier for claim 63 has been corrected from "Withdrawn-Currently Amended" to "Previously Presented". Withdrawal of the objection to claim 63 is thus respectfully requested.

# The Non-Statutory Obviousness-Type Double Patenting Rejections

Claims 1-3, 10-13, 32-34, 41-44, 63-78, and 150-151 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36, 38-78, and 96-111 of copending U.S. application Serial No. 10/890,825 in view of Padua (U.S. published application No. 2003/0204206). Claims 1-3, 10-13, 32-34, 41-44, 63-78, and 150-151 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of copending U.S. application Serial No. 11/220,397. Claims 1-3, 10-13, 32-34, 41-44, 63-78, and 150-151 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of copending U.S. application Serial No. 11/276,077.

Applicant notes that U.S. application Serial Nos. 10/890,825, 11/220,397 and 11/276,077 have not yet issued and are pending. Therefore, a terminal disclaimer is not required in these matters until issuance of one of them. If a terminal disclaimer is required in any of Serial Nos. 10/890,825, 11/220,397 and 11/276,077, it can be requested by the Office before issuance of those matters.

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### § 102 Rejection of the Claims

Claims 1-3, 13, 32-34, 44, 63-64, 67-73, and 150-151 were rejected under 35 U.S.C. § 102(a) and under § 102(e) as being anticipated by Padua et al. (U.S. published application No. 2003/0204206, herein "Padua").

### Claim 1

Claim 1 has been amended to better describe the recited subject matter. Support for the amendment is found, for example, on page 21, lines 19-22 and page 24, lines 7-15 of the present application.

Applicant respectfully traverses the rejection and submits that the Office Action does not set forth a proper *prima facie* case of anticipation because the cited portions of Padua do not provide the claimed subject matter. For example, Applicant is unable to find in the cited portions of Padua, among other things, a controller adapted to produce a gene regulatory control signal including parameters that quantitatively control the emission of the regulatory signal based on the one or more condition parameters, as recited in claim 1.

### The Office Action states, in paragraph 5:

Padua expressly discloses that the controller 92 is adapted to quantitatively control emission of regulatory signals from the gene regulatory signal delivery devices (i.e. electrodes), the quantitative control based on the determined one or more condition parameters (i.e. ST segment elevation or reduction of blood blow [sic] in the coronary sinus) ...

However, the cited portions of Padua merely relate to several parameters of electrical pulses as what the stimulation device "is able to deliver", or "preferred" values, or a "feature" (e.g., paragraphs 158, 175, and 176). Applicant is unable to find in Padua that such parameters are produced by its "controller 92" based on "ST segment elevation or reduction of blood flow in the coronary sinus", as opposed to, for example, predetermined prior to the detection of those events.

Applicant respectfully requests reconsideration and allowance of claim 1.

# Claims 2-3 and 13

Claims 2-3 have been amended to more clearly describe the recited subject matter. Support for the amendment is found, for example, on page 22, lines 3-6 and 10-14 of the present application.

# AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

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Applicant respectfully traverses the rejection. Claims 2-3 and 13 are dependent on claim 1, which is believed to be allowable for at least the reasons set forth above. Therefore, the

discussion above for claim 1 is incorporated herein to support the patentability of claims 2-3 and

13.

Additionally, the Office Action states, in paragraph 6, that "Padua further comprises an output pulse generator, read as an electromagnetic field generator 74" and "Padua expressly discloses that the field has a predetermined frequency of about 10 to 100 Hz". This assertion is respectfully traversed. The cited portions of Padua relate to electrical pulses delivered at 10 to 100 Hz. It is unclear how the electrical pulses could be an electromagnetic field being a regulatory signal which regulates transcription from a regulatable transcriptional control element, as recited in claim 3. Applicant respectfully requests a clarification in the next official communication, or withdrawal of the rejection.

Applicant respectfully requests reconsideration and allowance of claims 2-3 and 13.

### Claim 32

Claim 32 has been amended to better describe the recited subject matter. Support for the amendment is found, for example, on page 32, line 23 to page 33, line 3 of the present application.

Applicant respectfully traverses the rejection and submits that the Office Action does not set forth a proper *prima facie* case of anticipation because the cited portions of Padua do not provide the claimed subject matter. For example, Applicant is unable to find in the cited portions of Padua, among other things, an external controller adapted to automatically analyze signals acquired by an implantable medical device and generate an external command when deemed necessary as a result of the analysis, as recited in claim 32.

Applicant respectfully requests reconsideration and allowance of claim 32.

# Claims 33-34, 44, 63, 64, and 67-73

Applicant respectfully traverses the rejection. Claims 33-34, 44, 63, 64, and 67-73 are dependent on claim 32, which is believed to be allowable for at least the reasons set forth above.

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Therefore, the discussion above for claim 32 is incorporated herein to support the patentability of claims 33-34, 44, 63, 64, and 67-73.

Applicant respectfully requests reconsideration and allowance of claims 33-34, 44, 63, 64, and 67-73.

#### Claims 150-151

Applicant respectfully traverses the rejection. Claims 150-151 are dependent on claim 1 or 32, which are believed to be allowable for at least the reasons set forth above. Therefore, the discussion above for claims 1 and 32 are incorporated herein to support the patentability of claims 150-151.

Applicant respectfully requests reconsideration and allowance of claims 150-151.

# § 102/§ 103 Rejections of the Claims

Claims 10-12 and 41-43 were rejected under 35 U.S.C. § 102(a) and U.S.C. § 102(e) for anticipation by or, in the alternative, under 35 U.S.C. § 103(a)as obvious over Padua in view of Donahue et al. (U.S. published application No. 2002/0155101, herein "Donahue").

Applicant respectfully traverses the rejection. Claims 10-12 are dependent on claim 1. Claims 41-43 are dependent on claim 32. Claims 1 and 32 are believed to be allowable for at least the reasons set forth above. It is believed that the addition of Donahue does not remedy the deficiency of Padua as discussed above. Therefore, the discussion above for claims 1 and 32 is incorporated herein to support the patentability of claims 10-12 and 41-43.

Applicant respectfully requests reconsideration and allowance of claims 10-12 and 41-43.

### §103 Rejection of the Claims

Claim 65 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Padua et al. and/or under 35 U.S.C. § 103(a) Padua in view of Thompson et al. (U.S. Patent No. 5,902,324, herein "Thompson") or Kroll (U.S. Patent No. 6,865,420, herein "Kroll").

Claim 66 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Padua and/or under 35 U.S.C. § 103(a) Padua in view of Salo (U.S. published application No. 2003/0105493, herein "Salo").

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Claims 74-78 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Padua in view of Nelson (U.S. published application No. 2002/0072785, herein "Nelson").

Applicant respectfully traverses the rejection. Claims 65-66 and 74-78 are dependent on claim 32, which is believed to be allowable for at least the reasons set forth above. It is believed that the addition of any of Thompson, Kroll, Salo, and/or Nelson does not remedy the deficiency of Padua as discussed above. Therefore, the discussion above for claim 32 is incorporated herein to support the patentability of claims 65-66 and 74-78.

Applicant respectfully requests reconsideration and allowance of claims 65-66 and 74-78.

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### **CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 20 day of

February 2008.

RATE GUNDA

Signature

Name